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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,772	01/22/2002	Joseph R. Armstrong	MP/154A	9021

7590                    05/16/2003

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[REDACTED] EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/054,772	ARMSTRONG ET AL.	
	Examiner	Art Unit	
	Thomas J Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 March 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 43-48 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 3</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of group I claims 1-42 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton et al (US 6015431). Thornton et al discloses an endoprosthesis assembly comprising an implantable endoprosthesis in the form of a self-expanding stent (col 9, 161), a generally tubular delicate constraining sheath made of ePTFE (col 12, 14-6) with means for disruption (132) initiated by the application of a distending force. However, Thornton et al does not disclose using a packaging sheath. It is common knowledge in the prior art to package equipment in the art of surgical instruments for the purpose of keeping the equipment clean and sterile prior to use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the endoprosthesis assembly of Thornton et al in order to keep it clean and sterile prior to use.

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With regards to claims 2-10, 12-20, 22-30, and 32-40, Thornton et al discloses a constraining sheath of the same material (ePTFE) as the present invention, which would inherently perform the same as the present invention.

With regards to claims 41 and 42, the method limitation of storing at a temperature of less than 5 degrees C for 30 or 60 days imparts no structural limitation on the product of an endoprosthesis assembly, so the endoprosthesis assembly of Thornton et al structurally meets these claims.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sullivan et al. (US 6,533,806), Fontaine et al. (US 6,447,540).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018. The examiner can normally be reached on 6:30 am - 5:00pm M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.

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tjs

May 14, 2003



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700